Medicare Coverage Advisory Committee – Evaluative Questions

Obesity Patients With Co-morbidities

1. How well does the evidence address the effectiveness of Bariatric Surgery in the treatment of obesity in patients with co-morbidities compared to non-surgical medical management?

** 1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well*

1 2 3 4 5

2. How confident are you in the validity of scientific evidence available with respect to Bariatric Surgery re: outcomes in obese patients with co-morbidities?

** 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

1 2 3 4 5

3. How likely is it that the following procedures will positively affect the following outcomes in obese patients with co-morbidities? Circle the appropriate answer in each box.

Procedure / Outcome	**RYGBP**	**LRYGBP**	**VBG**	**BPD wi/wo DS**	**Lap BPD**	**No Surgery**
Wt Loss (sustained)	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Surgical Complications	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Long-term Survival Increased	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Short-Term Mortality	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Co-morbidities	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**

4. How confident are you that Bariatric Surgery will produce a clinically important net health benefit in the treatment of obese patients with co-morbidities?

** 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

1 2 3 4 5

5. Based on the scientific evidence presented, how likely is it that the results of Bariatric Surgery in obese patients with co-morbidities can be generalized to:

** 1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely*

a. The Medicare population (aged 65+): 1 2 3 4 5
b. Providers (facilities/ physicians) in community practice: 1 2 3 4 5

Glossary:

Obesity refers to "Class II Obesity" and "Class III Extreme Obesity." NIH defines "Class II Obesity" as BMI = 35.0 to 39.9 and Class III Extreme Obesity as BMI ≥ 40.

Co-morbidity. includes but is not limited to high risk factors such as history of MI, Type 2 diabetes, Hypertension and sleep apnea, etc, and may include reversal &/or prevention of same.

Validity. CMS uses "validity" here as defined by Meinert, "Validity, in the context of a treatment difference, refers to the extent to which that difference can be reasonably attributed to a treatment assignment." (Meinert CL. Clinical Trials, Overview. In: Redmond CK, Colton T, eds. Biostatistics in clinical trials. Wiley and Sons, 2001. pp. 37-51). This encompasses all issues of methodologic framework, study design, observed results, biological rationale, etc.

Net health benefit. CMS defines net health benefit as the balance between risks

RYGBP = Roux-en-Y Gastric Bypass

LRYGBP = Laparoscopic Roux-en-Y Gastric Bypass

VBG = Vertical Gastric Banding

BPD wi/wo DS = Biliopancreatic Diversion with or without Duodenal Switch

Lap BPD = Laparoscopic Biliopancreatic Diversion with or without Duodenal Switch

Medicare Coverage Advisory Committee – Evaluative Questions

Obesity Patients Without Co-morbidities

1. How well does the evidence address the effectiveness of Bariatric Surgery in the treatment of obesity in patients without co-morbidities compared to non-surgical medical management?

** 1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well*

1 2 3 4 5

2. How confident are you in the validity of scientific evidence available with respect to Bariatric Surgery re: outcomes in obese patients without co-morbidities?

** 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

1 2 3 4 5

3. How likely is it that the following procedures will positively affect the following outcomes in obese patients without co-morbidities? Circle the appropriate answer in each box.

Procedure / Outcome	**RYGBP**	**LRYGBP**	**VBG**	**BPD wi/wo DS**	**Lap BPD**	**No Surgery**
Wt Loss (sustained)	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Surgical Complications	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Long-term Survival Increased	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Short-Term Mortality	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**
Co-morbidities	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**	**1 2 3 4 5**

4. How confident are you that Bariatric Surgery will produce a clinically important net health benefit in the treatment of obese patients without co-morbidities?

** 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

1 2 3 4 5

5. Based on the scientific evidence presented, how likely is it that the results of Bariatric Surgery in obese patients without co-morbidities can be generalized to:

** 1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely*

a. The Medicare population (aged 65+): 1 2 3 4 5
b. Providers (facilities/ physicians) in community practice: 1 2 3 4 5

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Obesity refers to "Class II Obesity" and "Class III Extreme Obesity." NIH defines "Class II Obesity" as BMI = 35.0 to 39.9 and Class III Extreme Obesity as BMI ≥ 40.
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